Chemical name: oxytetracycline Type A medicated article (medicated feed)
Ingredients: monoalkyl trimethyl ammonium salt of oxytetracycline.

Current Label	Potential NADA Claim pending development of additional data
Species: Catfish **Indication:** Control mortalities resulting from bacterial hemorrhagic septicemia (*Aeromonas liquifaciens*) and pseudomonas disease **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration with the water temperature not less than 62° F. ***Withdrawal time after treatment is 21 days***	**Limitations/comments:** In a mixed feed ration with the water temperature not less than 62° F. Withdrawal time after treatment is ***<21 days.***[1] [1] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue.
Species: ***Scaled warmwater fish*** **Indication:** ***Control mortalities resulting from bacterial hemorrhagic septicemia (Aeromonas liquifaciens) and pseudomonas disease*** ***Not currently on the label - denotes label extension***	**Species:** ***Scaled warmwater fish***[1] **Indication:** ***Control mortalities resulting from bacterial hemorrhagic septicemia (Aeromonas liquifaciens) and pseudomonas disease*** **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration ***at all water temperatures used for culture.*** Withdrawal time after treatment is ***<21 days***[2]. [1] Note: Currently, no supporting INAD efficacy data are available to include scaled warmwater species on the label. The number of species, if any, included in the revision is directly related to the number of species included in the supporting INAD efficacy trials. [2] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue, however, no human food safety data are currently available for scaled warmwater fish. Requirements for additional data will be determined by CVM reviewers. UMESC also assumes that CVM will not require additional environmental safety data with the addition of these disease indications.

Current Label	Potential NADA Claim pending development of additional data
Species: ***Catfish*** **Indication:** ***Control mortalities resulting from columnaris disease (Flavobacterium columnare)*** ***Not currently on the label - denotes label expansion***	**Species:** ***Catfish***[1] **Indication:** ***Control mortalities resulting from columnaris disease (Flavobacterium columnare)*** **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration with the water temperature not less than 62° F. Withdrawal time after treatment is ***<21 days***[2]. [1] Note: Requires the development of pivotal efficacy data for catfish or a major aquaculture scaled species. [2] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue. UMESC also assumes that CVM will not require additional environmental safety data with the addition of these disease indications.
Species: ***Scaled warmwater fish*** **Indication:** ***Control mortalities resulting from columnaris disease (Flavobacterium columnare)*** ***Not currently on the label - denotes label extension***	**Species:** ***Scaled warmwater fish***[1] **Indication:** ***Control mortalities resulting from columnaris disease (Flavobacterium columnare)*** **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration ***at all water temperatures used for culture.*** Withdrawal time after treatment is ***<21 days***[2]. [1] Note: Currently, no supporting INAD efficacy data are available to include scaled warmwater species on the label. Assumes that pivotal efficacy data for catfish or a major aquaculture scaled species are developed and accepted and supporting INAD efficacy data are developed for a variety of warmwater species. The number of species, if any, included in the revision is directly related to the number of species included in the supporting INAD efficacy trials. [2] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue, however, no human food safety data are currently available for scaled warmwater fish. Requirements for additional data will be determined by CVM reviewers. UMESC also assumes that CVM will not require additional environmental safety data with the addition of these disease indications.

Current Label	Potential NADA Claim pending development of additional data
Species: ***Coolwater fish*** **Indication:** ***Control mortalities resulting from columnaris disease (Flavobacterium columnare)*** ***Not currently on the label - denotes label extension***	**Species:** ***Coolwater fish***[1] **Indication:** ***Control mortalities resulting from columnaris disease (Flavobacterium columnare)*** **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration ***at all water temperatures used for culture.*** Withdrawal time after treatment is ***<21 days***[2]. [1] Note: Currently, no supporting INAD efficacy data are available to include coolwater species on the label. Assumes that pivotal efficacy data for salmonids, catfish, or a major aquaculture scaled species are accepted for columnaris disease and supporting INAD efficacy data are developed for a variety of coolwater species. The number of species, if any, included in the revision is directly related to the number of species included in the supporting INAD efficacy trials. [2] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue and acceptance by CVM of human food safety data submitted by UMESC. UMESC also assumes that CVM will not require additional environmental safety data with the addition of these disease indications.
Species: ***Coolwater fish*** **Indication:** ***Control mortalities resulting from furunculosis (Aeromonas salmonicida), bacterial hemorrhagic septicemia (Aeromonas liqufaciens), and pseudomonas disease (Pseudomonas)*** ***Not currently on the label - denotes label extension***	**Species:** ***Coolwater fish***[1] **Indication:** ***Control mortalities resulting from furunculosis (Aeromonas salmonicida), bacterial hemorrhagic septicemia (Aeromonas liqufaciens), and pseudomonas disease (Pseudomonas)*** **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration ***at all water temperatures used for culture.*** Withdrawal time after treatment is ***<21 days***[2]. [1] Note: Currently, no supporting INAD efficacy data are available to include coolwater species on the label. The number of species, if any, included in the revision is directly related to the number of species included in the supporting INAD efficacy trials. [2] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue and acceptance by CVM of human food safety data submitted by UMESC. UMESC also assumes that CVM will not require additional environmental safety data with the addition of these disease indications.

Current Label	Potential NADA Claim pending development of additional data
Species: Salmonids **Indication:** Control mortalities resulting from ulcer disease (*Hemophilus piscium*), furunculosis (*Aeromonas salmonicida*), bacterial hemorrhagic septicemia (*Aeromonas liqufaciens*), and pseudomonas disease (*Pseudomonas*) **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** ***In a mixed feed ration above 9°C. Withdrawal time after treatment is 21 days.***	**Species:** Salmonids **Indication:** Control mortalities resulting from ulcer disease (*Hemophilus piscium*), furunculosis (*Aeromonas salmonicida*), bacterial hemorrhagic septicemia (*Aeromonas liqufaciens*), and pseudomonas disease (*Pseudomonas*) **Dosage Regimen:** 2.5 to 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration ***at all water temperatures used for culture.*** Withdrawal time after treatment is ***<21 days***[1,2]. [1] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue and acceptance by CVM of human food safety data submitted by UMESC.
Species: Salmonids **Indication:** ***Control mortalities resulting from bacterial coldwater disease (Flavobacterium psychrophilum) and columnaris disease (Flavobacterium columnare)*** ***Not currently on the label - denotes label expansion***	**Species:** Salmonids **Indication:** ***Control mortalities resulting from bacterial coldwater disease (Flavobacterium psychrophilum) and columnaris disease (Flavobacterium columnare)***[1] **Dosage Regimen:** 3.75 g/100 lb/day for 10 days **Limitations/comments:** In a mixed feed ration ***at all water temperatures used for culture.*** Withdrawal time after treatment is ***<21 days***[2]. [1] Note: Pivotal efficacy data in salmonids for both of these diseases have been or will soon be submitted to CVM for review. [2] Note: The withdrawal time will likely be considerably less than 21 days based on the revised tolerance of 2.0 Fg/g oxytetracycline in the tissue and acceptance by CVM of human food safety data submitted by UMESC. UMESC also assumes that CVM will not require additional environmental safety information with the addition of these disease indications.

The following claims are not revised:

Species: Pacific salmon **Indication:** Mark skeletal tissue **Dosage Regimen:** 250 mg/kg/day for 4 days **Limitations/comments:** For use on salmonids less than 30 g incorporated in the feed as the sole ration. Seven day withdrawal time after use. The hydrochloride salt of oxytetracycline may also be used.	**Species:** Lobster **Indication:** Control mortalities resulting from gaffkemia (*Aerococcus viridans*) **Dosage Regimen:** 1 g/lb medicated feed for 5 days **Limitations/comments:** Use in feed as the sole ration. Withdrawal time is 30 days after treatment